UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 20, 1990

Seth Goldberg
Steptoe & Johnson
1330 Connecticut Ave., N.W.
Washington, D.C. 20036-1795

Dear Mr. Goldberg;

Thank you for your letter of April 4, concerning an evaluation of the Isolyser System for compliance with the 40 CFR Part 259 regulations. As you are aware, the exclusion found in Section 259.30(b)(l)(iv) states that residues from treatment and destruction processes are no longer regulated medical waste (RMW) once the waste has been both treated and destroyed. The generator would therefore not have to track its waste from the point where the wastestream has been both treated and destroyed.

There are a number of methods a generator of medical waste can use to achieve treatment of medical waste. The Office of Solid Waste (OSW), as required in Section 11008(a)(6) and (7) of RCRA, as amended by the Medical Waste Tracking Act of 1988 (MWTA), is evaluating treatment technologies as part of the information included in the Reports to Congress. However, the MWTA did not give the Agency the authority to approve or disapprove medical waste treatment methods. The Agency would like to include the Isolyser treatment technology in its evaluation for these Reports.

The Part 259 regulations contain treatment and destruction performance criteria which is the basis for this evaluation. Treatment as defined in Section 259.10(a) is "any method, technique, or process designed to change the biological character or composition of any RMW so as to reduce or eliminate its potential for causing disease." Treated RMW is defined in Section 259.10(b) as "RMW which has been treated to substantially reduce or eliminate its potential for causing disease, but has not yet been destroyed." Historically, chemical disinfectants have commonly been used within the health-care setting to help control, reduce, or eliminate microorganisms within the work area. However, the use of chemical disinfecting for the treatment of various types of medical waste prior to disposal has not been thoroughly evaluated. We presume that those disinfectants which have been tested on a broad spectrum of microorganisms and comply with the requirements of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) as administered under the Office of Pesticides Programs (OPP), would be effective in the health-care setting to reducing potential for disease transmission associated with medical wastes.

As noted, the Office of Pesticides Programs (OPP) also evaluates disinfectants. Although the objective of their evaluation is different, the testing performed on disinfectants in this program would be

helpful to the evaluation of the Isolyser system as a medical waste treatment technology. Attached to your letter was a description of antimicrobial tests which have been performed on the disinfectant used in the Isolyser System. After review of the data which was submitted it appears that the chemical disinfectant is moderately effective for inactivation of non-spore forming bacteria and Aspergillus niger;, however, no information was submitted on the disinfectant's ability to inactivate viruses and tubercle bacillus. In addition, this disinfectant appears to be only moderately effective for inactivating spore forming bacteria.

It should be noted that the test results which have been submitted on the Isolyser system were performed on the disinfectant. No test results have been submitted indicating the effectiveness of the Isolyser system on medical waste.

Further, no information has been submitted to OSW on the actual disinfectant and its chemical characteristics. In order for OSW to thoroughly evaluate the Isolyser System, information concerning the disinfectant's chemical characteristics would be necessary. Specifically, OSW is concerned about any type of chemical used as a disinfectant for treatment of medical waste which is then to be land disposed. The use of chemicals which are hazardous wastes upon disposal would be subject to the RCRA Hazardous Waste regulations (40 CFR 260-268,270).

As noted in your letter, OSW must determine not only the ability or potential for a treatment technology to effectively treat medical waste, but also if that treatment technology meets the destruction definition in order to qualify for the exclusion found at Section 259.30 (b)(l)(iv). Destroyed RMW is defined in Section 259.10(b) as "RMW that has been ruined, torn apart, or mutilated through processes such a thermal treatment, melting, shredding, grinding, tearing or breaking, so that it is no longer generally recognizable as medical waste." The term "destruction" was included in the Part 259 regulations to ensure the waste was physically changed or altered in order to render the waste unrecognizable. While the definition of destroyed RMW does provide some latitude, within the scope of the definition, for development of destruction methods for medical waste, the Agency does not believe that encapsulation of RMW (especially sharps) in a gel-like medium contained in a plastic bottle meets the intent or definition of "destroyed RMW."

Thus, while the Isolyser System does appear to have a moderate ability to inactivate certain types of microorganisms, we are unable to adequately evaluate the chemical composition of the disinfectant used in the system. Additionally, the Isolyser System does not appear to meet the definition of destroyed RMW as defined in Section 259.10(b).

As you have requested, the information submitted to our office in regard to this evaluation will be maintained as confidential business information, not subject to public review. This response, however, is not confidential business information. Materials submitted for evaluation are not routinely returned to the submitter when the information is the basis for the regulatory evaluation. Additionally, under Section 11004 of RCRA we have the authority to collect data which will be included in the Report to Congress.

If you have further questions or required additional information, please contact Mary Greene at 202-475-7736.

Sincerely,

Devereaux Barnes, Director
Characterization and Assessment Division

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